PALOSTAT

PALONOSETRON HCL INN

Compositions:
Palostat Tablet: Each film coated tablet contains Palonosetron Hydrochloride INN equivalent to Palonosetron 0.5 mg. Palostat 0.075 mg IV Injection: Each ampoule contains 1.5 ml solution containing Palonosetron Hydrochloride INN equivalent to Palonosetron 0.075 mg. Palostat 0.25 mg IV Injection: Each ampoule contains 5 ml solution containing Palonosetron Hydrochloride INN equivalent to Palonosetron 0.25 mg.

Pharmacology:
Palonosetron is a 5-HT3 receptor antagonist with a strong binding affinity for this receptor. As a result, serotonin can't activates 5-HT3 receptors and thus fails to initiate vomiting reflux. Cancer chemotherapy may be associated with a high incidence of nausea and vomiting. 5-HT3 receptors are located on the nerve terminals of the vagus in the periphery and centrally in the chemoreceptor trigger. It is thought that chemotherapeutic agents release serotonin (5-HT) from the enterochromaffin cells of the small intestine. The released serotonin then activates 5-HT3 receptors located on vagal afferents to initiate the vomiting reflex. Postoperative nausea and vomiting is influenced by multiple patients, surgical and anesthesia related factors and is triggered by release of serotonin (5-HT) in a cascade of neuronal events involving both the central nervous system and the gastrointestinal tract. The 5-HT3 receptor has been demonstrated to selectively participate in the emetic response.

Dosage And Administration:
Usual dosage Adult tablet dosage: One 0.5 mg tablet/day Adult 0.075 mg IV dosage: A single 0.075 mg (1 ampoule) IV dose. Postoperative Nausea and Vomiting Adult IV dosage: A single 0.075 mg IV dose administered over 10 seconds immediately before the induction of anesthesia. Chemotherapy-Induced Nausea and Vomiting Adults tablet dosage: One 0.5 mg tablet administered approximately one hour prior to the start of chemotherapy. Adult 0.25 mg IV dosage: A single 0.25 mg IV dose administered over 30 seconds. Dosing should occur approximately 30 minutes before the start of chemotherapy. Child dosage: A single 1-3 mcg/kg (half ampoule) IV dose.

Contraindications:
Palonosetron is contraindicated in patients known to have hypersensitivity to the drug or any of its components.

Warning And Precaution:
Hypersensitivity reactions may occur in patients who have exhibited hypersensitivity to other selective 5-HT3 receptor antagonists.

Side Effects:
The most common adverse reactions in chemotherapy-induced nausea and vomiting (incidence 5%) are headache and constipation. The most common adverse reactions in postoperative nausea and vomiting (incidence 2%) are QT prolongation, bradycardia, headache, and constipation.

Use in Pregnancy and Lactation:
Pregnancy category B. It is not known whether Palonosetron is excreted in human milk.

Drug Interaction:
In vitro studies indicated that Palonosetron is not an inhibitor of CYP1A2, CYP2A6, CYP2B6, CYP2C9, CYP2D6, CYP2E1 and CYP3A4/5 (CYP2C19 was not investigated) nor

does it induce the activity of CYP1A2, CYP2D6, or CYP3A4/5. Therefore, drug interactions with Palonosetron appears to be low.

Overdosage:
There is no known antidote to Palonosetron. Overdose should be managed with supportive care.

Storage:
Store at controlled temperature of 20-25°C. Protect from light and keep out of the reach of children.

Packing:
Palostat Tablet: Each box contains 1X10 tablets in alu-alu blister pack. Palostat 0.075 mg IV Injection: Each box contains 1 ampoule. Palostat 0.25 mg IV Injection: Each box contains 1 ampoule.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.